OCT 11 2001

WORLD HEADQUARTERS
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K012807

510(k) Summary

This summary of 510(k) safety and effectiveness is being supplied in accordance with the Safe Medical Device Act of 1990 and 21 C.F.R.

807.92(a)

1. Standard Textile Co., Inc.
One Knollcrest Drive
Cincinnati, Ohio 45237

Contact Person: Brad Bushman
(513) 761-9255 Ext. 455
Summary Prepared on 6/29/01

2. Device Name: ComPel Surgical Drapes and Covers, non-sterile (75X reusable)
Common/Usual Name: Non-sterile Surgical Drapes and Covers
Classification Name: Fenestrated Surgical Drapes/Covers
Non-fenestrated Surgical Drapes/Covers
Regulation #878.4370

3. Predicate Device: ComPel Surgical Drapes #K923811

4. All base fabrics used in the construction of ComPel Surgical Drapes are made from 100% polyester, knitted or woven into fabric and then dyed. WrapPel and ComPel fabrics are fluorocarbon treated, XTR fabric is silicone coated, COMBOsafe fabric is laminated with a urethane film and Zorwik is treated to be hydrophilic.

ComPel Surgical Drapes will function as a surgical drape when processed according to instructions through 75 complete wash, dry and sterilization cycles. These products will be manufactured and distributed as non-sterile surgical drapes that are intended to be sterilized and processed by health care facilities and/or contract sterilization/laundry companies.

5. ComPel Surgical Drapes are intended to be used on patients or surfaces where protection from liquid migration is needed. The location and level of liquid protection as well as the size and location of a fenestration is defined by the surgical staff. The liquid barrier properties will inhibit the migration of liquids across its surface.

There are no critical differences in the use of this product from currently marketed ComPel Surgical Drapes (K923811) except for the use of the COMBOsafe fabric. ComPel Surgical Drapes have demonstrated that they will perform as intended when used as labeled.

6. The tests that have been successfully completed include:
   a. Flammability 16 CFR Part 1610.
   b. Barrier Performance
      i. Suter Hydrostatic Testing AATCC #127-1989
      ii. Mullens Hydrostatic Testing ASTM D751-95 Procedure A
   c. Strength ASTM #D-1682-87 & ASTM #D-3786-87
   d. Lint EDANA 220.0-96
   e. Toxicity - Cytotoxicity MEM Elution (MG023)
      Acute Systemic Toxicity (ISO 10993)
   f. Primary Skin Irritation (ISO 10993))
   g. Sterilization - Product sold non-sterile; can be sterilized using prevacuum steam cycles.
   h. Durability through 75 processing (wash, dry and sterilization).
   i. Colorfastness to Commercial Laundering - AATCC #61-1993(4A).

To the best of my knowledge, all data and information in the 510(k) are truthful and accurate, and that no material fact has been omitted.

Bradley J. Bushman

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 11 2001

Mr. Bradley J. Bushman
Director, Technical Resources
Standard Textile Company, Incorporated
One Knollcrest Drive
Cincinnati, Ohio 45237

Re: K012807
Trade/Device Name:ComPel Surgical Drapes
Regulation Number: 878.4370
Regulation Name: Nonsterile Surgical Drapes and Covers
Regulatory Class: II
Product Code: KKX
Dated: September 14, 2001
Received: September 18, 2001

Dear Mr. Bushman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER: K012807

DEVICE NAME: ComPel Surgical Drapes

INDICATIONS FOR USE:

ComPel Surgical Drapes are intended to cover patients or working surfaces during surgical procedures. ComPel Surgical Drapes and Covers are made of synthetic materials intended to be used as protective patient coverings, such as to isolate a site of surgical incision from microbial and other contamination.

ComPel Surgical Drapes will function as a surgical drape when processed according to instructions. The ComPel Surgical Drapes are reusable through 75 wash, dry and sterilization cycles. They are manufactured and distributed as non-sterile surgical drapes that are intended to be sterilized and processed by health care facilities and/or contract sterilization/laundry companies.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use
(Optional Format 1)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K012807